

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	10/016,752
Filing Date	October 30, 2001
First Named Inventor	Ramy Lidor-Hadas et al.
Art Unit	1625
Examiner Name	Taylor V. Oh
Attorney Docket Number	1662/55002

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
[Handwritten mark]		4,739,072	04-19-1988	Oxford et al.	
		4,783,478	11-08-1988	Wootton et al.	
		4,835,173	05-30-1989	Tyers	
		4,957,609	09-18-1990	Godfrey et al.	
		4,983,621	01-08-1991	Bunce et al.	
		5,478,949	12-28-1995	Bod et al.	
		5,629,333	05-13-1997	Young	
		5,712,302	01-27-1998	Young	
		5,854,270	12-29-1998	Gambhir	
		5,982,494	10-05-1999	Young	
		6,063,802	05-16-2000	Winterborn	
		6,388,091	05-14-2002	Lee et al.	
		2004/0019093	01-29-2004	Aronhime et al.	
		2005/0020655	01-27-2005	Molnar et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
[Handwritten mark]		EP 0 276 559 B1	08-03-1998	Tyers		
		EP 0 415 522 B1	03-06-1990	Collin		
		WO 02/36558 A2 (U.S. equivalent 2002/0107275)	05-10-2002	Lidor-Hadas et al.		
		WO 02/055492 A2 (U.S. equivalent 2002/0115707)	07-18-2002	Lidor-Hadas et al.		
		WO 03/090730 A1	11-06-2003	Ndzie et al.		

Examiner
Signature

[Handwritten Signature]

Date
Considered

4/11/06

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Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	10/016,752
		Filing Date	October 30, 2001
		First Named Inventor	Ramy Lidor-Hadas et al.
		Art Unit	1625
		Examiner Name	Taylor V. Oh
		Attorney Docket Number	1662/55002
Sheet	2	of	2

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
W		Pirttimaki, J., et al. "The Transformation of Anhydrate and Hydrate Forms of Caffeine at 100% RH and 0% RH, <i>European Journal of Pharmaceutical Sciences</i> , 1994, Vol. 1, pp. 203-208.	
		Iida, H., et al. "Intramolecular Cyclization of Enaminones Involving Arylpalladium Complexes. Synthesis of Carbazoles" <i>J. Org. Chem.</i> 1980, Vol. 45, pp. 2938-2942.	
		European Pharmacopoeia 4.4, Ondansetron Hydrochloride Dihydrate* 2003, pp. 3489-91.	
		Harry G. Brittain (Ed.) (1999) "Polymorphism in Pharmaceutical Solids" <i>Drugs and the Pharmaceutical Sciences</i> Vol. 95, pp. 183-226, Marcel Dekker, Inc. New York, New York.	
		Bym, S.R., et al. (Ed.) (1999) "Solid-State Chemistry of Drugs" Second Edition, pp. 59-67, SSCI, Inc. West Lafayette, Indiana.	
		Bym, S.R., et al. (Ed.) (1982) "Solid-State Chemistry of Drugs" pp. 6-7, Academic Press, New York, New York.	
		Threlfall, T.L., et al. "Analysis of Organic Polymorphs" <i>The Analyst</i> , 1995, Vol. 120, pp. 2435-2460.	
		Carless, J.E., et al. "Cortisone acetate crystals forms" <i>J. Pharm. And Pharmacology</i> , 1966, Vol. 18, pp. 190S-197S.	
		Chen, Chem Abstr., "Synthesis of Antiemetic Ondansetron" <i>Chinese J. of Pharmaceuticals</i> , 1993, 24(6), pp. 241-242 (Ch).	
		The United States Pharmacopeia (USP 27-NF22), 22 nd edition, First Supplement, April, 2004, pages 3030, 3075-3076.	
		The United States Pharmacopeia (USP 27-NF22), 22 nd edition, Second Supplement, August, 2004, pages 3234, 3283-3285.	
		The United States Pharmacopeia (USP 26-NF21), 21 st edition, The National Formulary, January, 2003, pages 1351-1352.	
		The Merck Index p. 6977 "Ondansetron", 1996.	
		Kim, M. Y, et al. "An Efficient Process of Ondansetron Synthesis" <i>Heterocycles</i> , 1997, Vol. 45, No. 10, p. 2041-2043.	

Examiner Signature		Date Considered	4/11/56
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